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Does walking outdoors have the same breast cancer protective effect as walking on a treadmill indoors, away from natural light, in a typical gym atmosphere? Is the ambient exposure to sunlight important in stress and breast cancer risk reduction? Our basic premise is that the breast cancer protective mechanisms of exercise depend on context of exercise, not just on the number of repetitive muscular contractions completed over a specific period of time, and that a more pleasant and peaceful environment will decrease perceived stress and enhance immunity, theoretically leading to more positive mood and more effective cancer surveillance. A more relaxed walking atmosphere may decrease physiological consequences of stress, such as decreasing salivary cortisol, alpha-amylase, and melatonin. Revisions to the original endpoints include adding 3 questionnaires to assess mood changes, and including of physiological measures of stress (alpha-amylase, melatonin, and cortisol). By focusing on the context of exercise (indoor versus outdoor), we will be able to better define the important aspects of exercise on breast cancer prevention.

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Do the Effects of Exercise on Breast Cancer Prevention Vary With Environment?

Introduction

The purpose of this study is to investigate whether exercise outdoors has the same breast cancer protective effect as exercise done indoors away from natural light in a typical gym atmosphere on a treadmill. It has also been suggested that sunlight, often a concomitant exposure associated with exercise, can reduce breast cancer risk. This raises the question of whether exposure to sunlight during exercise correlates with reduced susceptibility to breast cancer. The basic premise that the breast cancer protective mechanisms of exercise depend on context of exercise, not just on the number of repetitive muscular contractions completed over a specific period of time, and that a nicer, more peaceful environment will lead to more positive mood and more effective cancer surveillance. A more relaxed atmosphere and mindset could decrease physiological consequences of stress, such as cortisol, alpha-amylase, and melatonin. Revisions to the original endpoints include adding 3 brief questionnaires to assess mood changes, adding physiological measures of stress (salivary cortisol, alpha-amylase, and melatonin). Changes in these hormones are closely related to plasma levels, and provide a non-invasive method to estimate changes associated with walking exercise. We will also be measuring ambient light exposure in the two environments and sound levels in the two environments. By focusing on biomarkers of stress and mood, as modified by exercise and context of exercise (indoor versus outdoor), we will be able to better define the important aspects of exercise on breast cancer prevention.

Body of Report

Task 1. Develop Plan for Study Computer Database, Months 1-3

- We have decided to use the analytic services of Salimetrics, a company that specializes in analysis of saliva for hormones. This is based on their experience in doing more than 500,000 samples, and their ability to obtain reliable data in a timely manner.
- Access database will be developed to monitor each volunteer and to record data from laboratory analyses and medical histories.
- Tracking system is in place.

Task 2. Obtain IRB approval from local institutions (Palmetto Health Alliance and the University of South Carolina).

a. Done

Task 3. Obtain IRB approval from the U.S. Army

- HSRRB met on October 10, 2001 to review the grant.
- HSRRB Board members recommended approving this protocol with modifications October 19, 2001.
- Modifications were accepted
- However, no use of human subjects could begin until the University of South Carolina made arrangements for insurance, to be paid by the U.S. Army. Negotiations between the University of South Carolina and the US Army were completed in February 2003 but the HSRRB approval had expired.
- Based on new published literature and new understanding of the effects of exercise, this study was re-designed to include Quality of Life, and added physiological measures of stress (cortisol, melatonin, and alpha-amylase). These endpoints replace the blood-based endpoints of the previous proposal. This is based on the observation that venipunctures are perceived as significant sources of discomfort in the local population, and that saliva offers a reliable alternate endpoint that is more appropriate for measuring stress-related variables.
- The re-designed endpoints were submitted to the Human Subjects Protection Specialist in May 2003. The suggested changes to the study were accepted, and the protocol was expected to go to the HSRRB in October 2003. However, for some reason, no further action was taken until August, when my study was re-assigned to a new Human Subjects Protection Specialist. This new specialist felt that changing from blood based biomarkers to saliva based biomarkers constituted such a major change that a new proposal and a new local IRB approval was necessary. This has now been done, and my study is awaiting assignment to a new Human Subjects Protection Specialist.

Task 4. Subject Recruitment and Study, Months 1-2

- As soon as permission from the HSRRB is granted we estimate that recruitment to our study should be accomplished with in 2 months.
- Wendy McKenzie has been hired to recruit subjects.
- We will rely on word of mouth to recruit healthy postmenopausal women who regularly exercise and take no medications. The study for each participant will last 2 weeks.

Task 5. Shipping samples to Salimetrics and data analysis Months 3-8

- All samples will be stored until the completion of the walking study at which time we will ship the samples to Salimetrics. Estimated time to receive results is 3 weeks from the date of arrival.
- Data from the mood questionnaires, background information will be entered.
- Data will be analyzed

Task 5. Data Analysis of Results from Healthy Volunteers, Months 8-12

- Meetings with oncologists to present preliminary data.
- Meetings will take place as soon as the data are available.
- September 2005 all the analyses should be completed and articles submitted for publication.
- Final report to USARMC.

Key Research Accomplishments

- Narrowed the scope of the research to include only women living at approximately 300 ft (100 meters) in Columbia, South Carolina.
- Replaced Dr. Mark Davis, Director of Exercise Biochemistry Laboratory at the University of South Carolina with contract analysis of the samples by Salimetrics
- Refined the biological endpoints to include changes in salivary cortisol, melatonin, and alpha-amylase and added mood assessment questionnaires.
- Received approval from the University of South Carolina IRB for the new protocol and Informed Consent.

Reportable Outcomes

- None yet. Volunteers will be recruited as soon as possible (warm ambient temperatures for outdoor walking). Hopefully this can be accomplished during the fall of 2004.

Conclusions

- Human Subjects concerns and Scientific Review concerns have been met, and we are waiting for HSRRB final approval.
- Specific results of the study are not yet available.

References

- Not applicable

Appendices

- None yet.

List of Personnel

- P.I. Jane Teas, Ph.D.
- Project Director: Wendy McKenzie
- Statistician: Daniela K. Nitcheva, Ph.D.